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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,551	02/05/2004	David Edwards	000166.0109-US02	2801

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COVINGTON & BURLING, LLP  
ATTN: PATENT DOCKETING  
1201 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20004-2401

EXAMINER
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MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/771,551	<b>Applicant(s)</b> EDWARDS ET AL.	
	<b>Examiner</b> Kristen C. Matter	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-31,33-63 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-31,33-63 and 67-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/25/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 45 recites the limitation "the receptacle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4-9, 11-14, 16, 18, 24, 25, 27, 28, 29, 31, 33-40, 42-44, 46, 48, 50, 56, 57, 59, 60, 61, 63, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Silver et al. (US 2002/0020067).

Regarding claims 1, 4, 31, 34, and 37, Silver et al. disclose a cutting device with a substantially longitudinal prong (110), a sharp puncturing point on the distal end of the prong

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(see figure 11), a primary cutting edge (112) running from the proximal end of the prong to the distal end and terminating at the sharp point, a substantially planar face opposite of the primary cutting edge and running from the proximal end of the prong to the distal end of the prong (see figure 11). Use of the language “for” and “configured to” is considered intended use and therefore not given any patentable weight. Furthermore, because the powder capsule is not positively claimed, the hanging chad, which is part of the capsule, is not given patentable weight as a structure. The device disclosed by Silver et al. is inherently able of being used to puncture a powder capsule and for forming a hanging chad in the capsule wall.

Regarding claims 3 and 33, Silver et al. disclose a base (32) coupled to the proximal end of the prong.

Regarding claims 5-6 and 35-36, Silver et al. discloses that the cutting edge can be serrated (paragraph 0018). Examiner argues that aerated and jagged are synonymous.

Regarding claims 7 and 38, as seen in figure 11, the planar face has a slight concave curvature towards the distal end of the prong.

Regarding claims 8 and 39, the prong is tapered so that the distal end is smaller than the proximal end as seen in figure 11.

Regarding claims 9 and 40, Silver et al. disclose a beveled edge (paragraph 0018), and as seen in Figure 11, the beveled edge runs from the sharp point to the planar face at the distal end of the prong. The curved distal end of the prong can also, in itself, be considered an angled face that runs from the sharp point to the planar face.

Regarding claims 11-13 and 42-44, Silver et al. disclose that the prong can be made of metal, ceramic, or plastic (paragraph 0015).

Regarding claim 45, the prong disclosed by Silver et al. has a length and it is considered a design choice to insert the prong at least  $\frac{3}{4}$  of its length into a receptacle without breaking off a hanging chad. Again, because the powder capsule is not positively claimed, no patentable weight is given to its structure.

Regarding claims 14, 25, 46, and 57, the sides of the prong seen in Figure 11 comprise planar longitudinal edges between the cutting edge and the planar face running from the distal end of the prong to the proximal end.

Regarding claims 16, 18, 48, and 50, as seen in Figure 11, there are two longitudinal edges (on either side of the planar face) and 2 longitudinal faces disclosed by Silver et al.

Regarding claims 24 and 56, the longitudinal edges disclosed by Silverman et al. are blunt so as to avoid cutting the user.

Regarding claims 27-29 and 59-61, Silver et al. discloses an assembly with a plurality of puncturing prongs coupled to a base (31), wherein the assembly is substantially U-shaped as seen in Figure 10 between any two sets of prongs.

Regarding claims 10, 30, 41, and 62, Silver et al. discloses the claimed invention except the process by which the prong was made. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2<sup>nd</sup> 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Regarding claims 63 and 67, because the powder capsule is not positively claimed, no patentable weight is given to its structure (i.e., axes, hanging chad). Therefore, the device disclosed by Silver et al. has all of the claimed features of claim 63. Using the prong to form a hanging chad in a powder capsule with an angle of at least 30 degrees or between 30 and 45 degrees with respect to a minor axis is considered intended use language.

Claims 1, 14, 31, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerber et al. (US 3,752,027).

Regarding claims 1, 14, 31, and 46, Gerber et al. disclose a cutting tool with a longitudinal prong (66), a sharp puncturing point (63) on the distal end of the prong, a primary cutting edge (76), a substantially planar face (88) opposite of the cutting edge, and a plurality of longitudinal faces (80, 72, 74) and a plurality of longitudinal edges (86, 84, 78) running from the distal end of the prong to the proximal end (see Figures 4 and 5). Applicant is reminded of the argument with respect to intended use outlined above.

Claims 1, 14, 20, 21, 26, 31, 46, 52, 53, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 5,676,683).

Regarding claims 1, 14, 31, and 46, Yoon discloses a trocar with a substantially longitudinal prong comprising a sharp puncturing point (46) on a distal end, and a primary cutting edge, a substantially planar face (166), a plurality of longitudinal faces, and a plurality of longitudinal edges running from the distal end of the prong to the proximal end (see Figures 10 and 11). Applicant is reminded of the argument with respect to intended use outlined above.

Regarding claims 20 and 52, as seen in Figure 11, Yoon discloses a substantially triangular cross-section for the prong.

Regarding claims 21 and 53, the longitudinal edges disclosed by Yoon are sharp.

Regarding claims 26 and 58, the longitudinal faces disclosed by Yoon have a slight concave curvature (168) as seen in Figure 11.

Claims 68, 69, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill (US 4,617,929).

Regarding claim 68, Gill discloses a trocar with a substantially longitudinal prong (12), a sharp puncturing point, a primary cutting edge, and a substantially planar face as seen in Figure 6. Furthermore, Gill discloses a cover (72), which is capable of being used to place a powder capsule in for piercing. The cover itself is considered the casing with the aperture, the inside of the cover is considered the cylindrical chamber with straight edges of circular cross-section (closest to prong in Figure 7), and the notched portion with reduced internal cross-section is considered the ring coupled to the inner surface of the chamber.

Regarding claims 69 and 70, Applicant is reminded of the arguments with respect to intended use language outlined above. Therefore, the claims 69 and 70 do not differ in scope from claim 68 because the structure of the hanging chad is not given patentable weight.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 17, 19, 47, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerber et al. Although Gerber et al. do not explicitly disclose four longitudinal edges or faces, Gerber et al. do disclose that any number of conveying planes can be used to form the prong (column 5, lines 35-45). It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have provided the prong with four longitudinal faces, four longitudinal edges, or a substantially pentagon cross-section depending on the number of conveying planes used to form the prong and the desired notch shape.

Claims 22, 23, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon as applied to claims 1, 14, 20, 21, 26, 31, 46, 52, 53, and 58 above, and further in view of Stephens et al. (US 5,314,417). Yoon is silent as to the longitudinal edges being serrated or jagged. However, Stephens et al. disclose a trocar with serrated edges (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Yoon's trocar with serrated edges as taught by Stephens et al. in order to more easily cut through tissue.



***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-31, 33-63, and 67-70 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

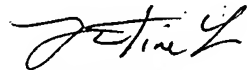
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter  
Examiner  
Art Unit 3771



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